

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K100341

MAY - 4 2010

1. Date of Summary: January 29, 2010
2. Submitted by: Princeton BioMeditech Corporation
4242 U.S. Route 1, Monmouth Jct., NJ 08852
Phone: 732-274-1000
Fax: 732-274-1010
3. Device Name: Trade Names: SpermCheck® Fertility
Common or Usual Name: Semen analysis test device
Classification Name: Obstetrics/gynecology
4. Identification of legally marketed devices to which claims of equivalence are made:
Hemacytometer
K073039, SpermCheck® Vasectomy Test by Princeton BioMeditech Corp.
K041039, Fertell Male Fertility Test by Genosis Ltd.
K011679, FertilMARQ™ Home Diagnostic Screening Test for Male Infertility,
by Embryotech Laboratories, Inc.
5. Device Description: SpermCheck® Fertility is an immunochromatographic test for the rapid, qualitative detection of sperm concentration.
6. Intended Use:
SpermCheck® Fertility is a qualitative test that detects sperm concentration at or above 20,000,000 sperm/mL. The test is intended for use as an aid in the determination of a man's fertility status. For *in vitro*, over the counter home use.
7. Substantial Equivalence:
SpermCheck® Fertility is substantially equivalent to the standard microscopic analysis (counting by Hemacytometer) based on WHO guidelines in its performance. The principles of action for the assay are substantially equivalent to k073039, SpermCheck® Vasectomy Test by Princeton BioMeditech Corp. and k041039, Fertell Male Fertility Test by Genosis Ltd. All three tests are Chromatographic Immunoassays to detect sperm concentration qualitatively. SpermCheck® Fertility is also substantially equivalent to FertilMARQ™ Home Diagnostic Screening Test for Male Infertility by Embryotech Laboratories, Inc., k011679, in detecting sperm by a colorimetric assay to determine subfertile sperm concentrations qualitatively.

Conclusion: SpermCheck® Fertility is substantially equivalent in determining sperm concentrations qualitatively to: standard microscopic analysis (counting by Hemacytometer); k073039, SpermCheck® Vasectomy Test by Princeton BioMeditech Corp.; k041039, Fertell Male Fertility Test by Genosis Ltd.; and k011679, FertilMARQ™ Home Diagnostic Screening Test for Male Infertility by Embryotech Laboratories, Inc.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Princeton BioMeditech Corporation
c/o Dr. Kyung-ah Kim
Director
4242 US Route 1
Monmouth Junction, NJ 08852

JUN 15 2012

Re: k100341
Trade/Device Name: SpermCheck® Fertility
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Date: February 3, 2010
Received: February 5, 2010

Dear Dr. Kim:

This letter corrects our substantially equivalent letter of May 4, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Maria M. Chan". The signature is written in a cursive, flowing style.

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100341

Device Name: SpermCheck® Fertility

Indications For Use:

SpermCheck® Fertility is a qualitative test that detects sperm concentration at or above 20,000,000 sperm/mL. The test is intended for use as an aid in the determination of a man's fertility status. For *in vitro*, over the counter home use.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Gene Philip
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K100341